K011297

JUN 2 0 2001

NIPRO MEDICAL CORPORATION
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SUMMARY OF SAFETY AND EFFECTIVENESS
Nipro® SafeTouch Safety Scalp Vein and Blood Collection Set

§807.92 (a)(1)

Contact Person: Luis Candelario
President

Date of Summary Preparation: June 11, 2001

§807.92 (a)(2)

Trade Name: Nipro® SafeTouch Safety Scalp Vein and Blood Collection Set

Common Name: Scalp Vein Set

Classification Name: Intravascular catheter (21 CFR §880.5200)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Nipro® Scalp Vein Set (K955053), Angel Wing Blood Collection and Infusion Set (K912563)

§807.92 (a)(4)

Description of Device: The Nipro® SafeTouch Safety Scalp Vein and Blood Collection Set that we intend to market consists of flexible tubing which is connected to a female luer connector and winged needle with an active sharps safety feature which is inserted into the patient's vascular system (short time use). The only modification to the subject device compared to K955053 is the sharps safety feature. (The Nipro® Scalp Vein Set was cleared previously by FDA under K955053 on November 6, 1995.) The sharps safety feature is operated through a release of latch mechanism whereby the user slides a winged cover over the needle as it is removed from the patient. Once the needle is covered, the safety cover latches

into place. The safety feature presented in this document is substantially equivalent to K912563.

The Nipro® SafeTouch Safety Scalp Vein and Blood Collection Set will be offered in 80 different configurations with options to include needle gauge, needle length, and tubing length. The devices are packaged sterile and for single use only. They are restricted to sale by or on the order of a physician.

§807.92 (a)(5)

Intended Use:

The Nipro® SafeTouch Safety Scalp Vein and Blood Collection Set is intended to be used for insertion into the patient's vascular system (for single use) as an indwelling device to administer fluids intravenously or to sample blood. Secondly, it is designed with an active sharp feature requiring physical action by the clinician to aid in the prevention of needle stick incidents.

§807.92 (a)(6)

Comparison of Technical Characteristics:

Results of testing support the equivalence of the subject device to current legally marketed devices. Nipro Medical Corporation considers the Nipro® SafeTouch Safety Scalp Vein and Blood Collection Set to be substantially equivalent to the marketed Angel Wing Safety Blood Collection and Infusion Set with regard to intended use, materials, biocompatibility and overall performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2001

Nipro Medical Corporation
C/O Ms. Kaelyn B. Hadley
Consultant
C.L. McIntosh
1384 Copperfield Court
Lexington, Kentucky 40514-1268

Re: K011297
Trade/Device Name: Nipro® SafeTouch Scalp Vein and Blood Collection Sets
Regulation Number: 880.5200 and 880.5570
Regulatory Class: II
Product Code: FOZ and FMI
Dated: April 27, 2001
Received: April 30, 2001

Dear Ms. Hadley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) number (if known): K011297
Device name: Nipro® SafeTouch Safety Scalp Vein and Blood Collection Set
Indications for use: The Nipro® SafeTouch Safety Scalp Vein and Blood Collection Set is intended to be used for insertion into a patient's vascular system (for single use) as an indwelling device to administer fluids intravenously or to sample blood. Secondly, it is designed with an active sharp safety feature that requires physical action by the clinician to aid in the prevention of needle stick incidents.

(Please do not write below this line- continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ (Per 21 CFR 801.109)

OR

Over-The- Counter-Use____ (optional Format 1-2-9)

Viola Hubbard for Pat Cicenia
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011297